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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,798	10/21/2003	Jay Edelberg	1676.001US2	5627
21186 7590 11/14/2007 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402				
EXAMINER MALLARI, PATRICIA C				
ART UNIT 3735		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/690,798

**Applicant(s)**

EDELBERG ET AL.

**Examiner**

Patricia C. Mallari

**Art Unit**

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 30 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 59-78 and 81-107 is/are pending in the application.
- 4a) Of the above claim(s) 59-73, 77 and 85-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 74-76, 78, 81-84 and 107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2003 and 09 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This is a final Office action. Any new grounds of rejection were necessitated by the applicants' amendments to the claims.

#### ***Response to Amendment***

The amendment filed 8/30/07 was received and entered.

#### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the platelet derived growth factor claimed in claim 107 as being part of the sensor must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

Art Unit: 3735

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 107 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 107 recites, "the biosensor according to claim 74, further comprising platelet derived growth factor". The instant application discloses that the tissue or cells of the sensor may have been engineered to produce platelet-derived growth factor (see p. 12 of the instant specification), but fails to describe a sensor that *comprises* such platelet-derived growth factor.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3735

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Or

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 74, 76-78, and 80-83 are rejected under 35 U.S.C. 102(b) as being anticipated by over US Patent No. 5,368,028 to Palti. Palti teaches an implantable physiological or pathophysiological biosensor comprising cells (see entire document, especially col. 9, lines 16-31 of Palti) coupled to an electrical interface (see entire document, especially col. 6, lines 14-19; col. 11, lines 4-25 of Palti) and adapted to be electrically coupled to endogenous tissue or cells when implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject (see entire document, especially col. 6, line 66-col. 7, line 9; col. 11, line 44-col. 12, line 26 of Palti). The cells are adapted to electrically couple with endogenous tissue or cells via the transmission means, such as the transmitter that sends the processed signals through the skin, the implanted electrodes and amplifier for generating an electric field, or an induction coil or coupling capacitive signal transferor. The cells are capable of monitoring a chemical, physiological, or pathophysiological variable associated with the physiological or pathophysiological function of the subject (see entire document, especially col. 9, line 16-col. 10, line 34 of Palti) and are further

capable of producing at least a hormone, wherein beta cells from the islets of Langerhans, for example, are capable of producing insulin, which is a hormone.

As to the language “in vitro or ex vivo modified stem cells”, the applicant should note that this is “product-by-process” language, wherein the structure implied by the process steps, rather than the process itself, is given patentable weight. See MPEP 2113. In the case of “in vitro or ex vivo modified stem cells”, the structure implied by the process of modifying stem cells either in vitro or ex vivo are merely other developed or differentiated cells. For example, beta cells may be produced by modifying stem cells in vitro or ex vivo. Claim 76 contains more language regarding the process by which the cells are produced, wherein the process language again implies no more than another cell, such as a beta cell, which may be produced by cellular engineering.

As to the language “when implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject”, the applicants should note that this is merely “intended use” language which cannot be relied upon to define over the prior art, since Palti teaches all of the claimed structural limitations and their recited relationships. Ex parte Masham 2 USPQ2d 1647 (BPAI 1987). The device of Palti is certainly capable of implantation at any site in a mammalian subject in which size permits, wherein the site may clearly be distant from a natural site for a physiological or pathophysiological function of the subject, and further is certainly capable of being electrically

Regarding claim 75, beta cells, for example, are capable of producing vascular endothelial growth factor (VEGF).

Regarding claim 78, the physiological or pathophysiological variable is a level or activity of at least blood glucose (see entire document, especially col. 9, lines 25-55 of Palti).

Regarding claims 80-82, the biosensor clearly appears capable of being implanted into any mammal. The language "when implanted into a mammalian subject" is "intended use" language which cannot be relied upon to define over the prior art, since Palti teaches all of the claimed structural features and their recited relationships. Ex parte Masham 2 USPQ2d 1647 (BPAI 1987).

Regarding claim 83, the cells are incorporated within a device (see entire document, especially col. 10, line 41-col. 12, line 61 of Palti).

Claims 74-76 and 80-84 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2003/0211088 to Field. Field teaches an implantable device comprising in vitro or ex vivo modified stem cells coupled to an electrical interface 12 and adapted to be electrically coupled to endogenous tissue or cells when implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject (see entire document, especially fig. 1; paragraphs 13, 18, 23-25, 40-42, and 62 of Field). The cells (cardiomyocytes) can monitor a chemical, physiological, or pathophysiological variable associated with the physiological or pathophysiological function of the subject, wherein the applicants' specification identifies cardiac cells/cardiomyocytes as capable of such monitoring (see p. 9, line 25-p.10, line 9; p.11, lines 4-6; p. 22, line 25-p.23, line 15 of

the instant specification, for example), and cardiomyocytes can produce at least a growth factor, such as a vascular endothelial growth factor.

As to the language "when implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject", the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since Field teaches all of the claimed structural limitations and their recited relationships. Ex parte Masham 2 USPQ2d 1647 (BPAI 1987). The device of Field is certainly capable of implantation at any site in a mammalian subject in which size permits, wherein the site may clearly be distant from a natural site for a physiological or pathophysiological function of the subject.

The examiner notes the use of the term "biosensor" in the preamble of claim 74. However, the term fails to denote any structural features not already present in the device of Field. Furthermore, Field teaches all of the structural features claimed in the body of claim 74 and their recited relationships as set forth above. If the device of Field lacks a structural feature necessary for its function as a "biosensor", then it would appear that the applicants have failed to include an essential element of the invention.

Regarding claim 75, cardiomyocytes are capable of producing vascular endothelial growth factor (VEGF).

Regarding claim 76, the cells are genetically engineered (see entire document, especially paragraphs 23-28 of Field).

Regarding claims 80-82, the device is capable of being implanted in any mammal.

Regarding claims 83 and 84, the cells are incorporated within a device such as an electronic pacemaker (see entire document, especially fig. 1; paragraphs 40, 41, and 62 of Field).

### ***Response to Arguments***

Applicant's arguments filed 8/30/07 have been fully considered but they are not persuasive.

The applicants state that Palti reference "fails to disclose" a listing of "elements" on pp. 10-11 of the response, all of which were addressed in the rejection set forth in the previous Office action and repeated above. As to the first two elements in the listing, the examiner has already explained that the language "in vitro or ex vivo modified stem cells" is product-by-process language, wherein the product of Palti appears to be substantially identical to the structure implied by the applicants' process steps. The burden is on the application to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See MPEP 2113. The applicants have not provided such evidence nor have they addressed the examiner's treatment of the language at all as product-by-process language at all.

As to item (3) from the listing, the claim recites, "adapted to be electrically coupled to endogenous tissue or cells when implanted into a mammalian subject at a site distant from a natural site of a physiological or pathophysiological function of the subject", wherein the implantation of the cells at a distant site is merely a *use* of the claimed invention. The sensor of Palti is certainly capable of such implantation in any

part of the body, and further, is certainly capable of being electrically coupled to endogenous tissue or cells at such a site. For example, such coupling may take place by direct contact with such tissue or cells.

As to items (4) through (7), claim 74 merely states that the cells "can produce" one of these substances. Such language only requires that the cells be *capable* of such production. Again, as stated in the previous Office action and above, beta cells from the islets of Langerhans, which may be used in the sensor of Palti (see entire document, especially col. 9, lines 25-31 of Palti) are known to be capable of insulin production and insulin is a hormone (see, for example, the entry for "insulin" from the Encyclopaedia Britannica online; lines 23-27 of col. 1 of US Patent No. 3,683,635; lines 58-61 of col. 6 of US Patent No. 4,622,956; and lines 9-10 of col. 1 of US Patent No. 4,959,392).

The remainder of the applicants' remarks with regard to the Palti reference appear to address non-claimed differences between the invention of Palti and the applicants' own invention as well as a listing of more words that fail to appear in the Palti reference. Neither of these is pertinent to rejection of the claims as being anticipated by Palti. With further regard to the listing of words that Palti allegedly fails to disclose, the examiner has already repeatedly explained how Palti teaches the claimed invention and further notes that different language may certainly be used to describe the same thing. The rejection of claims as being anticipated by the Palti reference stands.

Regarding the Field reference, the applicants contend that Field "fails to disclose at least the element relating to implantation into a mammalian subject at a *site distant* from a natural site for a physiological or pathophysiological function". Again, as stated in

the previous Office action, addressed in the rejection above, and also addressed in the response to arguments regarding the Palti reference, the language "cells . . . adapted to be electrically coupled to endogenous tissue or cells when implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject" taken from claim 74 is merely "intended use" language which fails to result in result that is structurally different from the cells used in Field. The cells of Field *are* indeed capable of being so implanted and further of being so coupled. The applicants argue that "the fact that the present biosensors are capable of detecting a physiological or pathophysiological function at sites distant from the natural site for that physiological or pathophysiological function means that the cells of the present invention have properties that Field's cells do not necessarily have". Claim 74 does not recite that the cell monitors the function while the cell is implanted at a site distant from the natural site for that function. Claim 74 merely recites that the cell is capable of being electrically coupled to endogenous tissue or cells when implanted a site distant from the natural site for that function, wherein the cells, "can monitor a chemical, physiological or pathophysiological variable associated with the physiological function of the subject". Therefore, the intended use is the implantation and electrical coupling of the tissue or cells, and not the detection of a function at a site distant from the natural site for that function. Even if the detection of such function were the intended use, the applicants still have failed to provide any proof that there is a structural difference between these cells.

As with the production of insulin by beta cells from the islets of Langerhans in the Palti reference, cardiomyocytes are similarly known to be capable of production of VEGF (see, for example, "Pulsatile Stretch Stimulates Vascular Endothelial Growth Factor (VEGF) Secretion by Cultured Rat Cardiac Myocytes" by Seko et al. and "Signal Transducer and Activator of Transcription 3 is Required for Glycoprotein 130-mediated Induction of Vascular Endothelial Growth Factor in Cardiac Myocytes" by Funamoto et al.) Claim 74 only recites that the cells "can" or be capable of production of a growth factor.

Therefore, Field indeed explicitly and inherently discloses every element of the claimed invention. The rejection of claims as being anticipated by the Field reference also stands.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. C. M./  
pcm

/Robert L. Nasser/  
Primary Examiner, Art Unit 3735

